## GENTLE STOOL SOFTENER- docusate sodium capsule, liquid filled Walgreen Company

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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#### Walgreens 44-655-Gentle-Delisted

#### Active ingredient (in each liquid-filled capsule)

Docusate sodium 100 mg

#### **Purpose**

Stool softener laxative

#### Uses

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 12 to 72 hours

#### Warnings

#### Do not use

if you are presently taking mineral oil, unless told to do so by a doctor.

#### Ask a doctor before use if you have

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that lasts over 2 weeks

#### Stop use and ask a doctor if

- you have rectal bleeding or fail to have a bowel movement after use of a laxative.
   These could be signs of a serious condition.
- you need to use a laxative for more than 1 week

#### If pregnant or breast-feeding,

ask a health professional before use.

#### Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

#### **Directions**

- take with a glass of water
- take only by mouth. Doses may be taken as a single daily dose or in divided doses.

adults and children 12 years and over	take 1 to 3 capsules daily
children 2 to under 12 years	take 1 capsule daily
children under 2 years	ask a doctor

#### Other information

- each capsule contains: sodium 6 mgVery Low Sodium
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- protect from excessive humidity
- see end flap for expiration date and lot number

#### Inactive ingredients

anhydrous citric acid, edible white ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitol

#### Questions or comments?

1-800-426-9391

#### Principal display panel

#### Walgreens

#### **Gentle Stool Softener**

Compare to Dulcolax® Stool Softener active ingredient††

NDC 0363-0655-56

• Gentle & easy relief of occasional constipation

DOCUSATE SODIUM 100 mg / STOOL SOFTENER LAXATIVE

#### 25

LIQUID GELS

**ACTUAL SIZE** 

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

DISTRIBUTED BY: WALGREEN CO. 200 WILMOT RD., DEERFIELD, IL 60015

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Walgreens Pharmacist Recommended Walgreens Pharmacist Survey ††This product is not manufactured or distributed by Sanofi-Aventis Deutschland GMBH, owner of the registered trademark Dulcolax® Stool Softener.

50844 REV0218A65556

#### Walgreens

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NDC 0363-0655-56

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**Drug Facts** (continued)

B-2201-655-56-H REV0218A65556

ORG0418-F2 REV1219

sak a doctor	children under 2 years
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	loopon

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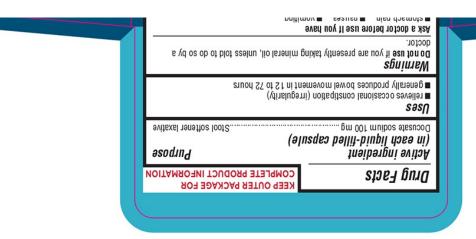
■ noticed a sudden change in bowel habits that lasts over 2 weeks

# No print/No varnish Lot & Exp date

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

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## DISTRIBUTED BY: WALGREEN CO. 200 WILMOT RD. DEERHELD, IL 60015 100% SATISFACTION GUARANTEED Walgreens.com ©2018 Walgreen Co. PRODUCT OF CHINA, PACKAGED AND QUALITY ASSURED IN THE U.S.A. TEM 411797 W00000-0000-0



Walgreens 44-655

#### **GENTLE STOOL SOFTENER**

docusate sodium capsule, liquid filled

<b>Product</b>	Inform	ation
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<b>Product Type</b>	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0655
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**Route of Administration** ORAL

#### **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	100 mg

Strength

Inactive Ingredients

**Ingredient Name** 

ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)
FD&C RED NO. 40 (UNII: WZB9127XOA)
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)

**GLYCERIN** (UNII: PDC6A3C0OX)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3MQ0SDW1A)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

WATER (UNII: 059QF0KO0R)
SORBITOL (UNII: 506T60A25R)

Product Characteristics				
Color	orange (Clear)	Score	no score	
Shape	OVAL	Size	13mm	
Flavor		Imprint Code	655	
Contains				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:0363- 0655-56	1 in 1 CARTON	03/01/2015	02/24/2023		
1		25 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				

Marketing Information					
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date					
OTC monograph not final	part334	03/01/2015	02/24/2023		
	part334	03/01/2015	02/24/202		

#### Labeler - Walgreen Company (008965063)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
LNK International, Inc.		832867837	pack(0363-0655)		

Establishment					
Name	Address	ID/FEI	Business Operations		
LNK International, Inc.		038154464	pack(0363-0655)		

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
LNK International, Inc.		868734088	pack(0363-0655)		

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
LNK International, Inc.		967626305	pack(0363-0655)	

Revised: 11/2021 Walgreen Company